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The Competing Policy Paradigms of Agricultural Biotechnology: Implications and Opportunities for Emerging and Developing Economies

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Agricultural science and technology policies—including public funding of crop genetics research, intellectual property protections, and biosafety approvals of regulated crops—can be understood to work together within a 'policy paradigm' to influence the innovation and adoption of crop varieties involving agricultural biotechnologies. The political-economy or public-choice approach views a given policy paradigm as a behaviorally rational response by policymakers to the range of pressures and inducements—such as political connections, lobbying, political donations, endorsements, elections, and popular movements—arising from the various segments of society and their respective interest groups. This article seeks to use the political-economy approach to explain why it is, almost twenty-five years after the disruptive technology of genetic engineering was first commercially deployed in crop agriculture, that most countries have a policy paradigm for transgenic crop varieties that resembles the traditional policy paradigm for the chemical pesticide industry rather than the traditional policy paradigm for the seed industry. This more restrictive policy paradigm, we argue, favors the incumbents of agricultural input industries over the interests of almost all others in society, including (most) farmers and consumers. Moreover, we argue that—perhaps counterintuitively—it is consistent with the interests of the incumbents of the crop input industries for public opinion of crop biotechnology to remain relatively negative or at least uncertain. This can be seen as a rational strategy to minimize biotechnology's potential to disrupt the industry. Implications are then drawn for the potential of public-sector research and smaller entrepreneurial businesses in agricultural input markets to realize the broader economic potential of crop biotechnology, including seeking to establish alternative policy paradigms for newly emerging genetic and breeding technologies.

Key words: biotechnology, regulatory policy, intellectual property policy, science funding policy, public choice, political economy.

Introduction

Biotechnology is both a general purpose enabling technology and a source of radical innovation. Biotechnology enables innovation across multiple industries, and within each industry it enables a wide array of process and product innovations, some of which can be disruptive of the established industry order. The new products and processes enabled by biotechnology can represent radical departures from established products and technologies in existing markets and industries, potentially displacing them. In agriculture, for example, biotechnology has presented an opportunity to introduce a variety of genetic traits into farming systems around the world that replace, compete with, or otherwise affect the value of existing production techniques and products.

As a result, the rise of biotechnology has driven changes and adaptations of previously existing policies governing agriculture and its products. An entire range of policies' impact upon the innovation and adoption of agricultural biotechnologies, including public research investments, intellectual property (IP), trade, biosafety, food safety, and product labeling, among others (Paarlberg & International Food Policy Research Institute [IFPRI], 2001). All of these areas of policy have had to adapt to some extent, in country after country. The rise of biotechnology has driven, for example, changes in public support for agricultural science. Biotechnology

has prompted an expansion of IP protections into new areas of subject matter—including invented biomolecules, invented biomaterials, and even invented living organisms. These new IP protections have, in turn, affected the incentives for early-stage research and technology commercialization. Biotechnology has also given rise to new regulatory standards for agricultural and food products. These separate areas of policy each do not act in isolation. Rather, they interact to shape the policy environment.

There has been wide divergence in science and innovation policies for agricultural biotechnology in different countries around the world. The public debate over these policies has often been quite polarized. After almost two decades of commercial use in the United States, Canada, Argentina, Brazil, and other countries, it seems to proponents to be well established that the major commercial transgenic crop traits such as herbicide tolerance and Bt insect resistance can be grown and consumed safely in corn, soybeans, and other common crops. Yet, detractors—especially in Europe, Japan, and many developing and emerging economies—continue to question health and environmental safety, resulting in policy environments that effectively discouraged or limited the innovation and adoption of biotechnologies in agriculture. This divergence has had two profound effects in agriculture and food.

First, by not adopting existing commercial biotechnologies, countries forego a number of technical welfare and environmental characteristics of the technology. Analyses have shown that agricultural productivity gains from biotechnology can contribute to lower prices, reduce pressure to expand land area for agriculture, reduce demand for water and other agricultural inputs, and reduce wastes generated such as pesticide and fertilizer runoffs (Sexton & Zilberman, 2010). Analyses suggest that the price effect of not allowing biotechnology has a negative impact on European consumer welfare (Neilson & Anderson, 2001). Wealthy European consumers may be able to afford a 'go-slow' precautionary approach to adopting biotechnologies, and it may indeed be economically rational if value of risk preferences is taken into account. For other countries, such policies can appear irrational from the point of view of general economic welfare. Why is it, for instance, that low-income developing economies model policies for agricultural biotechnology after wealthy Europe's restrictive standards, even though it means that poor farmers and poor urban consumers in those countries end up losing out on potential gains in agricultural productivity and food security (Paarlberg, 2009)? Moreover, within farming systems characterized by limited capacity for pest control—such as small-scale cotton growers in India—the introduction of biotech insect-resistance traits can bring significant yield gains (Qaim & Zilberman, 2003). Despite this, Indian regulators seemed determined to block Bt cotton technology until overwhelmed by the public reaction of cotton farmers (Herring, 2008).

A second effect of restrictive or uncertain policies on biotechnology is the increased costs and reduced incentives to innovate in other biotech traits or agricultural products (Graff, Zilberman, & Bennett, 2009). There are a number of possible innovations that would likely be far more advantageous in developing and emerging economies where biotechnology is currently not supported. Some traits are obviously important—such as drought tolerance or micronutrient biofortification (Mayer, Pfeiffer, & Bayer, 2008)—and others are more subtle—such as increased digestibility of animal feed. Foregoing innovation across the full potential range of applications of biotechnology, however, means foregoing feasible intensification in crop yields as well as foregoing gains in the use-efficiency of crop products, both of which reasonably would translate into economic and environmental gains.

These two results—the non-adoption by many countries of already existing and proven first-generation traits and the slowdown in innovation of a wide range of second-generation traits—may be attributed to the policy environment discouraging innovation or adoption of biotechnology, as well as the apparent political unwillingness of some governments to implement functioning policies at all. Some countries, such as the United States or Argentina, find it reasonable and politically feasible to adopt a policy paradigm—or set of interrelated policies—that supports the innovation and adoption of biotechnology. These policies have facilitated the rapid adoption of the technology by their agricultural sectors. Other countries, such as Europe and many developing countries, have found it unreasonable or politically unfeasible. What explains these differences?

Specifically, we question the notion that regulatory differences between the United States and Europe, or between Brazil and India, simply reflect differences in underlying consumer attitudes. Analysis has suggested that, initially, European and US consumer attitudes toward biotechnology were not significantly different (Gaskell, Bauer, Durant, & Allum, 1999). As a critique to consideration of just consumer attitudes, we seek to bring into consideration the welfare interests of all stakeholder groups that may be influential in framing

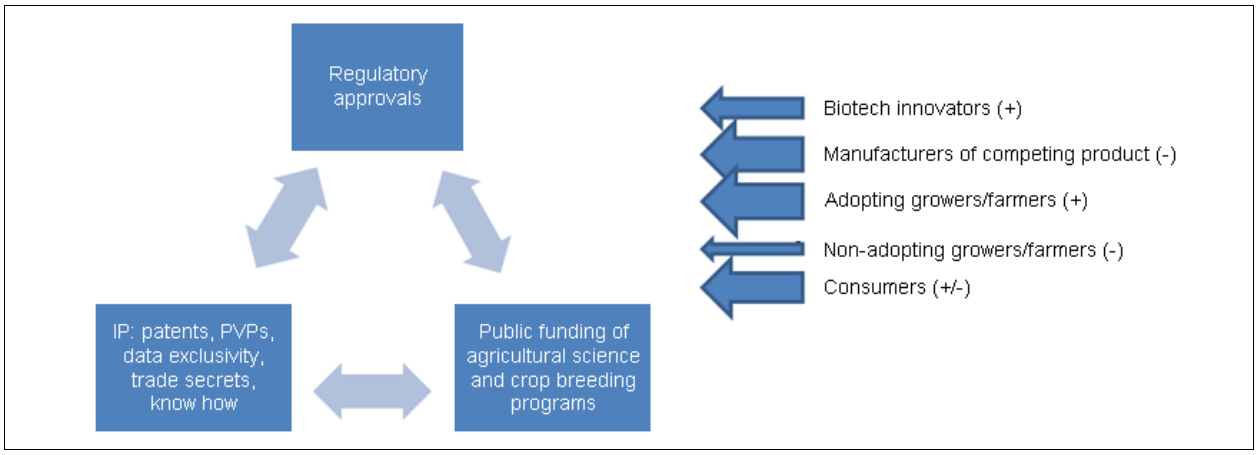

Figure 1. Various stakeholder groups assert their influence upon the formation of the broader policy paradigm that governs crop genetic development.

the public debate and politically influencing the policy-making process (Figure 1). Graff and Zilberman (2004) first broached the question directly as to whether European policies towards agbiotechnology might reflect strategic interests of the chemical industry and politically influential farm interests and whether consumer acceptance of the technology was possibly endogenous to policy formation processes informed by those interests. This line of reasoning was applied specifically to the formation of IP protections in Europe, based on an observation that a relative lack of inventions by European inventors in the agricultural life sciences meant there was a lack of domestic champions inside Europe to extend patent law to cover genetically engineered plants (Graff & Zilberman, 2004). Similar questions have been asked concerning the policy calculus of influential interests like generic chemicals manufacturers and export oriented farmers in developing countries (Graff, Hochman, & Zilberman, 2009). This article seeks to further develop this line of inquiry. Is it possible to explain differences in national science and innovation policies towards a disruptive enabling technology such as biotechnology by understanding how the economic interests of different parts of an economy are impacted by that technology, and understanding how interest groups interact as they seek to influence policymakers in their bids to protect and advance their respective economic interests?

Public Choice Theory and Agricultural Biotechnology Policy

Rooted in questions raised by Schumpeter about incentives for incumbents of industry to innovate (Schumpeter, 1942), the recent literature on the political economy of science and innovation policies follows the larger political economy literature that began with several seminal papers (i.e., Becker, 1983; Posner, 1974; Stigler, 1971) that laid the foundations for theories advanced by economists and political scientists to explain the behavior of regulators and the shape and strength of the policies that they make (Grossman & Helpman, 2001). Such theories typically take into account the influence that groups of regulated economic agents—such as producers and consumers—have on regulators, including the prospect that, in the extreme, such groups may effectively "capture" regulators (Stigler, 1971).

More sophisticated political-economic models have been designed to accommodate more features of political systems (Dixit, Grossman, & Helpman, 1997; Grossman & Helpman, 1995, 2001; Peltzman, 1976; Zusman, 1976). Most of these reduce to a policymaker or regulator that weighs the interests of a number of various groups within the economy, i.e., groups that have managed to solve the collective action problem and are well enough informed with respect to their likely costs or benefits arising from the regulations in question. A few scholars have extended static political-economic models to a dynamic setting and used the extended framework to explain long-run growth (Acemoglu, Johnson, & Robinson, 2005), as well as the survival of obsolete, yet politically connected companies.

Policy Paradigms

The next step is to examine the core assumptions and public choice rationale of the policy paradigm that has

emerged to govern the innovation and adoption of biotechnologies in agriculture. By 'policy paradigm' we refer to the suite or set of policies that interact to regulate the industry. More than a quarter of a century since most of these policies were first formed in the United States, there have come to be a number of well-rehearsed *prima facie* arguments worldwide within policy circles and the scholarly literature that make certain assumptions about reality as given. Whether representing the 'pro' or the 'con' position relative to a particular policy, these arguments today serve primarily to perpetuate and reinforce the prevailing policy paradigm. Following Paarlberg and IFPRI (2001) we consider several types of policies that impact innovation and adoption of agricultural biotechnology (illustrated in Figure 1).

Public Funding of Agricultural Research, Including Crop Genetic Research and Breeding Programs. The first major set of policies involves the public funding of agricultural sciences, and more specifically of crop genetics. It is a policy decision of a government to allocate funds toward agricultural research expenditures, whether at government laboratories, public or non-profit agricultural research institutes, or agricultural universities.

Intellectual Property Protections for Newly Developed Plant Genetics or Plant Varieties. The second set of policies that significantly affect the development of agricultural biotechnologies are those that govern the granting and enforcement of intellectual property rights (IPRs). This includes a range of different types of IPRs—utility patents, plant breeders' rights, trade secrets, know-how, and regulatory data exclusivity. Each of these is governed by a different realm of IP law, and as such each constitutes a separate area of policy in itself. Yet, what we typically see is that those entities developing crop genetics—both private-sector companies and public-sector research institutions—use a combination of several forms of IP to protect a newly developed crop variety; for example, a plant breeder's certificate to a hybrid variety, together with a trade secret regarding the parental lineage of the hybrid, and finally a trademark over the variety name, all working together. IP protections such as patents or trademarks typically fall to an Intellectual Property Office, often within a Ministry of Commerce. Agricultural- or plant-specific types of IP may be administered by a Ministry of Agriculture.

Administrative Regulations Over the Environmental Release, Commercial Cultivation, Commercial Sale, and Labeling for Feed and/or Food Use of Transgenic Crops. Third, there are policies restricting or requiring approval for certain production practices or products within a given country or multinational jurisdiction. These can include restrictions of the release of a particular organism such as a transgenic crop into the environment, or the import of a particular commodity for feeding livestock, or the marketing of a particular food product for human consumption. Such regulatory restrictions and authorizations typically fall to a Ministry of Environment, Ministry of Commerce, or Ministry of Agriculture, respectively.

Policies in each of these three areas have been highly contested in country after country when it comes to the use of biotechnology in agriculture. While the outcomes of those policy contests have differed rather significantly across countries (Anderson & Jackson 2004), the contests themselves have emerged as roughly similar across countries. Policy paradigms, as the patterns or combinations of policies governing agricultural science funding, IP protection, and regulatory requirements, have largely converged across countries.

Economic Welfare Impacts of Agricultural Biotechnology Policies on Key Stakeholder Groups

A correct disaggregation of society into relevant economic interest groups is crucial to understanding the alignment of economic interests within a given jurisdiction. There are innumerable ways to segment the stakeholder groups within society in order to account for the distribution of welfare impacts resulting from a public-policy decision. In reviewing the political economy of environmental policies, Oates and Portney (2003, p. 337) contend that, "in any particular application … the identification and characterization of the relevant interest groups is an essential and challenging part of the analysis."

Much of the potential social welfare gains from introducing the technology, particularly in developing countries, are likely to be broadly distributed across poor consumers and small farmers who may not have strong influence over policymaking because of their relatively small individual stakes, lack of knowledge and expertise concerning the technology, and relatively ineffective collective action. On the other hand, more concentrated economic interests, including incumbent agrochemical manufacturers, farm groups, and environ-

mental protest activists, may be much better organized and have clear economic incentives to maintain policies that block or slow the introduction of biotechnology. Distinguishing the relevant groups follows several rules of thumb.

Following typical welfare analysis, it is possible to dissect the economy into producers, consumers, and others "external" to the markets or sectors in question (such as the general public or the environment). Next, it is possible to subdivide each of these into subgroups where members within each given group are likely to experience similar welfare impacts but where expected impacts are likely to be different across subgroups, to the extent that they may even have conflicting or competing interests. For example, we would disaggregate export-oriented commercial farmers from domestic subsistence farmers, given that producer surplus of the former are likely to be affected differently by the adoption of (and thus by the regulation of) agricultural biotechnologies than the welfare of the latter. Moreover, these different subgroups are likely to have different degrees of influence over policy based upon the extent to which they have managed to solve the collective action problem, have become informed with respect to their own likely costs or benefits, and have developed an effective representation or 'lobby' with the politician or regulator.

We have identified several groups, some of which are more dispersed (i.e., less concentrated) than others with respect to the benefits and costs associated with undertaking collective action to represent their interests as a group:

i. *Biotech innovators:* First, the most obvious group of stakeholders impacted by public policy decisions are the biotech innovators. To what extend do these innovators win or lose under a policy promoting genetic innovation in agriculture?
ii. *Competing input manufacturers:* Next, and perhaps less obvious, are manufacturers of competing agricultural inputs. For the first generation of agricultural biotechnologies introduced to commerce, including insect resistance and herbicide tolerance traits, the most directly competing inputs include conventionally bred seeds and agricultural chemicals (specifically, insecticides and herbicides). A range of companies—many quite large and globally influential—have such inputs competing in the marketplace. Biotech traits, delivered in newly improved seed, can substitute for and thus displace those current products. Manufacturers of displaced agrochemical products are thus at risk of losing market share, and therefore stand to be negatively impacted by policies promoting genetic innovations.
iii. *Biotechnology adopting farmers:* The third group of stakeholders consists of farmers who choose to adopt the new technology. Farmers are constantly making economic decisions about what kind of seeds to plant or what kind of germplasm to incorporate into their production operations, as well as what other inputs—such as fertilizer or pesticide—to apply, and how much. Those who utilize a technology are making an economic decision based on expected profitability or reduced risk. Farmers will adopt a new technology if they assess that the new technology is better than existing alternatives and is likely to have a positive impact on them in terms of their economic welfare as producers.
iv. *Non-adopting farmers:* Another group of stakeholders to consider are non-adopting farmers. They may sell the same harvested product into the downstream market as those farmers who have taken up the technology. Yet, the non-adopting farmers continue to use the old technology and the old seed variety, and thus continue to face old cost structures and yields. If the new seed variety becomes widespread and it has the effect of increasing yields, it will begin to shift the aggregate supply curve for the harvested product in such a way that will begin to reduce the output price for the harvested product. That shift in price, of course, affects all farmers. However, those who have not adopted the new variety have lower productivity and are hurt more severely by the relative decrease in commodity prices. So, whether or not a farmer adopts the new technology, that farmer will be impacted by it. In fact, it is essential to divide farmers into those who benefit and those who stand to lose. Considering farmers as a single aggregate group would yield mixed results and mixed political signals, and would thus result in a general misunderstanding of the impacts of biotechnology within the farm sector.
v. *Consumers*: Finally, it is essential to consider the welfare impact of the policy paradigm on consumers. This stakeholder group can be consolidated to consist of the entire value chain, reaching from the farm gate to the final consumer. So, grain handling companies, traders and brokers, food manufacturers, wholesalers, and retailers are all potentially impacted by the policy paradigm. For simplification, however, it is possible to sweep all of those together under the title of 'consumer,' meaning in this case, any and all who buy product from farmers.

Each of these five stakeholder groups will weigh in on the policymaker's shaping of the policy paradigm according to their own particular point of view with regards to its impact on social and economic welfare. Most significant to each group, naturally, will be the impact of adopted policies on their own economic well-being. To the extent that stakeholder groups' interests are similarly affected, those groups will tend to be aligned politically. For example, while biotechnology innovators will weigh in on shaping the policy paradigm in order to get the policy paradigm adjusted toward their benefit, manufacturers of competing inputs will also weigh in, seeking to shape the policy paradigm in a manner that will benefit them. These two may be aligned with each other. However, it is also possible that they will be in conflict with each other, to the extent that they are competing for market share of farm input sales. When there is conflict of economic interests, there can be expected to be a contest of ideas within the policy-making process.

To fully appreciate the inner workings of the political economy, it is important to account for the fact that each of these different stakeholder groups has a different capability to exert political influence over the policy-maker, each has a different political weight. There is a common tendency for particular stakeholder groups—such as farmers or for the chemical pesticide industry—to have greater degrees of influence over particular departments of government. For example, farmers may have more influence within a Ministry of Agriculture, while chemical pesticide manufacturers may have more influence over a Ministry of Commerce or Ministry of Environment. A common result, thus, is that different ministries or agencies of a government may become locked in a power struggle regarding which has authority over which aspects of the policy paradigm, with the different parts of government each expressing the divergent interests of the stakeholder groups with which they are aligned.

In general, the amount of influence exerted by each stakeholder group within society depends on two factors: 1) how much is at stake for the members of that group and 2) how easily or costly it is to mobilize collective action among the members of that group. The principle of 'rational ignorance' (Stigler, 1971) explains that, even if the aggregate impact upon a large group may be significant, when each individual member of a group has relatively little at stake, it may be rational for each of the individuals within that group to take little interest in the policy, i.e., it is economically rational for them to remain uninformed or 'ignorant' regarding that policy. Consider Indian consumers. If agricultural biotechnologies were to be approved in India, each consumer may gain perhaps just a few rupees per year in the form of lower food or clothing costs. And while each individual Indian consumer thus has little incentive, the aggregate impact across all 1.2 billion Indians could tally up to an enormous sum in terms of consumer welfare. Still, because at the individual level the benefits are so small relative to the transaction costs of informing and mobilizing, it is not in fact rational for consumers to weigh in collectively to influence the policy paradigm that governs the innovation and adoption of crop genetics in India. In fact, rational ignorance tends to characterize consumers' relationship with food-policy issues in many countries around the world. While consumers, considered in aggregate, may be affected very significantly, the magnitude of impact on any individual consumer is so small that the individual typically does not raise a finger until a dramatic event puts the issue at the center of public attention.

The discussion becomes all the more illuminating when we are able to quantify the aggregate economic impacts of agricultural biotechnology policies upon these different stakeholder groups. A number of welfare analyses have estimated the total economic benefits and costs to stakeholder groups from several of the first-generation biotech crop (National Research Council, 2010). Some impacts on stakeholder groups are obvious and expected. On the benefits side, for example, the seed industry that sells Bt seeds realizes a profit. Also, growers of the Bt crop consist of those farmers that have adopted the technology this market year because it is profitable despite the higher seed costs, whether from reduced pest damage or reduced expenditures on pesticide spraying.

Such results may be counter to common expectations. For example, the impacts within the farm sector are indeed mixed, with some farmers benefitting while others suffer from the lower prices resulting from the technology shift. It is not possible to generalize that the technology is "good for farmers" or "bad for farmers." Thus, the political forces brought to bear by the farm sector upon the policymaker tend to be mixed.

Also, it is often overlooked that there are losses realized by pesticide manufacturers resulting from the reduction in chemical spraying by the Bt growers. In a few cases, these losses are internal to the same company that sells the new biotech seeds. However, in most cases, including generic chemical manufacturers, there is simply a loss of sales. The dynamics of competition that this sets up within the pest-control industry will be discussed

further below. But, it is very important to realize that the default political position of the agrochemical industry should not be assumed to be in support of policies favorable to biotechnology.

Finally, consumers make up the single largest group in terms of the economic value of Bt technology, benefitting due to the reduction in food prices (including meat products from livestock that are fed on the cheaper maize). However, due to the fact that there are about 300 million American consumers, the individual consumer realizes a benefit of less than US$2 per year. Thus, it is reasonable that the individual consumer does not think that his/her family benefits from agricultural biotechnology. At the same time, the gross benefit to consumers collectively is more than a half billion US dollars.

The Policy Paradigm of the Pesticide Industry versus the Policy Paradigm of the Seed Industry

While perhaps thousands of different transgenic traits have been expressed in plants experimentally, effectively only two types of trait have been widely commercialized—Bt insect resistance and tolerance to the herbicide glyphosate. Policy reports during the early days of agricultural biotechnology featured long lists of potential traits—ranging from vitamin levels to disease resistance to stress tolerance. During that era of the technology's development a protracted struggle was waged between effectively two possible policy paradigms for how agricultural biotechnologies should be governed: the policy paradigm of the seed industry and the policy paradigm of the pesticide industry.

The policy paradigm of the seed industry—heavily dependent upon public-sector research and breeding programs, relatively light IP protections, and minimal regulatory hurdles—could have been viable, and, were it adopted, would have ushered many safe transgenic products to market. Not the thousands that have been tested experimentally, but likely dozens, if not hundreds. But, the seed industry policy paradigm lost out or was crowded out.

Instead, the policy paradigm of the pesticide industry has come to prevail in most countries where a functioning policy has in fact been adopted. This, however, was not necessarily because of the risk profile of the new biotechnologies. Rather, the policy paradigm of the pesticide industry won out because biotechnology *could* compete in the pest-control markets; because the genetic traits of Bt insect resistance and herbicide tolerance competed against other (chemical) pest-control products, they effectively became interpreted and regulated as pesticides, subject to the same regulatory paradigm. In the process, the object of regulation became the transgenic event, defined by the method of engineering transgenes, and not the characteristics of the crop variety being grown (Bradford, Van Deynze, Gutterson, Parrott, & Strauss, 2005). Effectively, policymakers—subjected to the alignment of political pressures from various stakeholder groups—have settled upon rules to regulate any and all uses of this technology as if they were pesticides, not as if they were new seed varieties. As a result, costs of regulatory compliance for any and all uses of this technology are significantly higher than they would have been under the alternative policy paradigm. Other potential uses of biotechnology—even for genetic traits that have long been a routine focus of breeding efforts in the seed industry—were simply priced out of the market. The policy paradigm of the pesticide industry effectively erected a barrier to entry and, thereby, greatly narrowed the practical applications of the technology.

Why Have We Converged Upon the Policy Paradigm of the Pesticide Industry for Governing Agricultural Biotechnology?

Let us begin with a potentially naive question: *Why is a transgenic crop a regulated technology?* How strong is the precedent for governments to restrict the freedom of farmers to grow new varieties of established crops?[1] What is it that makes 'genetically engineered,' 'genetically modified,' or 'transgenic' a meaningful concept for policy purposes, setting it apart from any other sort of new crop variety? The *prima facie* argument is, of course, that early methods of plant transformation utilized certain genetic mechanisms of known plant pathogens, such as *Agrobacterium tumefaciens*, Cauliflower Mosaic Virus, and others, introducing the theoretical potential that transgenic plants using these technologies might be vectors of plant pathogenicity, even if their mechanisms were completely disabled. Regardless of the original rationale, most regulatory reviews and approval processes came to embrace a much wider interpretation of potential risks to be considered and regulated when developing transgenic crops, cultivating them in the open environment, or consuming them as food. But, it is worthwhile to question critically whether this scope of regulation is in fact supported by the nature of crop genetics.

1. *Of course, governments do strictly control some plant species, such as noxious weeds or plants producing narcotics.*

According to some plant scientists (Bradford et al., 2005; Potrykus, 2010), the method of making a crop with new genetics is largely unrelated to the objective level of risk posed by the resulting plant to environmental quality or human health. Rather, what matters is the nature of the traits as physically expressed in the environment or the food product. It is not the method of creating the genotype, it is the resulting phenotype; not "how" the genetic variation is achieved, but "what" that genetic variation produces.

This stands up to precedent. After all, plant varieties with genetic traits achieved by genetic engineering are often comparable to those found in nature or already in agricultural practice. Insect resistance traits are, naturally, a common part of many plant genomes, expressing toxins within the plant tissues that are naturally evolved defenses against pest predation. Many of these natural phytotoxins have high target specificity, similar to the Bt trait, and have been selected for by plant breeders over decades. Indeed, without them, agriculture would exhibit much lower yields in many crop species. Tolerance to herbicides such as imidazolinone has been induced by mutations and bred into crop varieties, currently marketed as competitors to the transgenic herbicide-tolerant varieties; however, because they are not transgenic, they are able to enter the market unregulated. For most traits, there might not be any more risk or need for public oversight of a new transgenic crop than there would be for other newly bred crops with novel traits. Indeed, the policy paradigm of the seed industry, focused on the nature of the expressed trait, would likely suffice to protect environmental and public health of most transgenic crops.

While risk management does stand as a plausible justification for some of the novel traits introduced using biotechnology, there may, in fact, be other, additional rationale for the kind of strict policy paradigm that has been adopted—again, patterned after what we see in the pesticide industry. Let us propose two reasons: first, the pressures of competition within the pest-control industry itself; and, second, the additional control that can be asserted over the technology in addition to (or in place of) IP alone.

Competition in the Regulatory Arena

Competition within the pest-control industry has long been played out in the arena of environmental and safety regulations. Simply put, even if minimal environmental and market safety regulations are in place, firms can be expected to use those regulations against rivals in seeking a competitive advantage. While the stated goals of regulatory requirements are to assure cleaner and safer pesticides, firms will engage in public comment, lobbying, and litigation efforts to influence environmental and safety standards in ways that favor their own products and disfavor their competitors. The regulator, thus, to some extent becomes a strategic ally to be manipulated against the opponent. Indeed, profitability for a firm can be significant if a competing product in a given market category is denied regulatory approval. A most desirable position, as a chemical pesticide company, is to be selling the only approved product within a given market, thus effectively enjoying a sanctioned monopoly. This is, of course, a classic argument of rent-seeking behavior. Moreover, once there is one product in a given market, the second comer will earn at best only a duopolist's returns. After two are in a given market, incentives for the third and then the fourth entrants diminish rapidly to the level of competitive economic profits. Moreover, if development and regulatory costs are sufficiently high, they can serve as an effective deterrent against those second, third, or fourth comers who might otherwise seek to enter a given market. The resulting competitive dynamic among leading firms has a tendency to ratchet up the stringencies and technical complexities of regulatory requirements, as well as costs.

Control Rights

While the dynamics of competition to gain advantage in the regulatory arena has a second salutary effect for the prevailing incumbent firms, the high costs of regulatory compliance create an effective barrier to entry against upstart entrepreneurs that could otherwise erode the incumbents' profitability. In effect, success in the regulatory approval process imparts a kind of 'control right' that complements, in important ways, the degree of control available under IPRs, which may be quite minimal in some countries.

In fact, in many countries, what patent law allows to be defined as an invention under a '*composition of matter*' or 'artic*le of manufacture*' patent claim is precisely that which becomes the object of the regulatory approval process. A company competing in pest-control markets will thus accept an implicit deal: the costs may be high to get the essential technology that constitutes a product approved, and some potential products may even be blocked by regulators. However, in exchange, if an IP-protected product gets approved, the exclusivity in the market achieved under the control rights effectively conferred by achieving that regulatory approval will be

reinforced by the control rights conferred by IP protections.

Interestingly, in those countries where IP protections are weak, the regulatory approval process alone can impart a sufficient degree of exclusivity in the market. In fact, under the extreme case, an innovator does not really need IP. Regulatory approvals alone, and the costs of attaining them, can impart at least some market power to the first firm to achieve them.

One example of this was Bt cotton in the Indian market in 2002-2005. During this period, the lead innovator was a joint venture between Monsanto and Mahyco. But these firms did not have any patents in India over the actual genetic construct, the *cry1ac* (Bollgard I) gene. According to our search of the Indian patent literature during these years, there was nothing in force in India by way of IP protection of the Monsanto-Mahyco Bollgard I technology. Yet, for a number of years, it was the only Bt cotton that had biosafety approval from the Indian government. Kathage and Qaim (2011) show that, following the Indian government's approval of Monsanto-Mayhco's Bollgard I in 2002, it was not until 2006 that three new genetic constructs were introduced: a second-generation Monsanto technology, an event originated from Indian Institute of Technology Kharagpur first approved in 2006, and an event from the Chinese Academy of Sciences also first approved in 2006. During this time period, each new cotton variety that contained the Bollgard I event (the *cry1ac* gene) also needed to achieve a similarly thorough and costly biosafety approval. So, any competing seed company with different cotton varieties, even if able to legally utilize breeding materials with the Monsanto-Mahyco Bollgard I genetics, since there was no patent, was not allowed to sell the resulting variety on the market because the resulting variety was a regulated object since the 'transgenic' trigger condition for regulations had been met.

Any company that successfully bred the *cry1ac* genetic construct into its own germplasm had two routes to follow: 1) they could run all the biosafety tests required to generate all of the requisite data reporting to comply with regulatory requirements, which would cost millions of rupees (expenditures which, from the point of view of assuring environmental or human safety, would largely be redundant); or 2) they could approach Monsanto and Mahyco to request access to the data they had generated to achieve regulatory approvals under Indian law for the initial Bollgard I cotton, which the company could then use to achieve approval for their new variety. Follow-on companies had access to the product technology, but they did not have access to the associated regulatory data and information necessary to fulfill the requirements of the regulatory approvals process.

In fact, since it was costly to generate new data and documentation for the Bollgard I event, and the data and documentation was accessible under a license with Monsanto, virtually all interested companies went this route, as it was the economically more advantageous route. But, in effect, it allowed Monsanto-Mahyco an opportunity to collect rents on the value of their regulatory data portfolio—rents entirely generated by the requirements posed by the Indian government. Monsanto-Mahyco enjoyed several years thereafter as the predominant vendor of Bollgard I cotton. In the following years, the original Bollgard I was taken off the market. Monsanto's Bollgard II became the most common technology available, while these other entrants provide significant competition in the marketplace (Herring, 2008). But, during the initial window of four years, Monsanto-Mahyco had a virtual monopoly position without a single patent, by virtue of the regulatory regime.

Reinterpreting the Rhetoric

Two arguments are routinely voiced in support of the emerging policy paradigm in agricultural biotechnology: one concerns the necessity of strong biosafety regulations and the other concerns the practical necessity of strong IPRs for innovation to continue. Both of these arguments, however, need to be reinterpreted in light of the political economy indicated by the distribution and magnitude of welfare impacts discussed above.

The first argument is that biosafety regulations are necessary to protect consumers and the environment. There are both strong and weak forms of this argument. The strong form is associated with the *precautionary principle*, which argues that regulatory preemption is necessary to minimize the risk from sources where the probability of occurrence or levels of damages in the event of occurrence are unknown or unestablished. The weaker version of the protection argument is associated with better-characterized risks and establishes thresholds intended to contain that risk within acceptable or safe levels. It is necessary to establish, however, that safety is objectively any higher under stronger regulations. Precautionary regulations are likely effective when damages are marginal or chronic, and their causes are difficult to detect, such as non-point-source pollutants or other forms of negative externalities that are necessarily difficult or costly to trace.

However, given that stronger regulations can serve to protect the incumbent industries' interests, even as they protect consumers or the environment, it at least must be acknowledged that there is a convergence of interests between the ascendant biotechnology innovators and consumers for some degree of protections. For the industry, regulations put in place indeed provide protection from new entrants and thus to a certain degree from competition. It effectively shifts some of the liability in the event of a problem away from the industry and onto the regulator who is partly responsible for safeguarding consumers and the environment.

The second argument is that strong IPRs are necessary to provide sufficient incentive to innovators to invest in the development and testing required to achieve regulatory approvals. However, particularly in biology where it can be difficult to establish the equivalence to a product that has achieved regulatory approval, it is not always the case that there will be a flood of follow-on copycats selling products that free-ride on the regulatory approvals achieved by the lead innovator. Control rights resulting from regulatory exclusivity, at least over a limited time window, may be sufficient in many cases for a lead innovator to earn sufficient returns to justify their investments. More likely, it is the synergistic effect between IP exclusivity and regulatory exclusivity that provokes the argument for IP protections. For in an environment of stringent regulation, the addition of strong IPRs is all the more advantageous for leading innovators to achieve.

How Convergence upon the Policy Paradigm of the Pesticide Industry is Impacting Research and Development in Agricultural Biotechnology

What we have seen for transgenic crops is the emergence of a policy paradigm modeled on that of the pesticide industry. This policy paradigm partly emerged from the competition in the industry that leads to a ratcheting up of regulatory scrutiny, but it at least is tolerated and is even favored by the leading innovators in industry, largely because of the control rights that it confers, and thus the rent-seeking that it enables. The paradigm is not opposed by consumers fundamentally due to the phenomenon known as 'rational ignorance,' where the costs of the policy are spread in diffuse fashion over a large population. Moreover, most consumers are assuaged that such a policy paradigm is essential for assuring safety and ongoing innovation. As long as enough farmers profit from the new technologies that are made available, the farm lobby will at least tacitly support such a policy paradigm. Convergence upon this 'high' equilibrium of the pesticide industry, rather than the potential alternative 'low' policy equilibrium of the plant-breeding and seed industry has consequences for the development of new products, in the form of improved seeds and crop varieties.

Skewing Innovation Toward Applications for Large Markets

The first result of this policy paradigm is to skew innovation processes towards those technologies that can be applied in large markets. The incentives are very strong to develop large market technologies because of the potential to capture sizeable rents and because of the fixed up-front costs for entering any market. Observation of the innovation dynamics going on in the industry concurs that indeed only a handful of large-market products have been commercialized, despite significant amounts of research and development (R&D) on a wide range of products.

It is important to underline here that the apparent economies of scale in agricultural biotechnology are almost entirely due to regulatory costs. The technology itself, embodied as it is in individual seeds is inherently almost scale-neutral. When even just a handful of transgenic seeds are grown, the technology works as well as if hundreds of hectares are grown.[2]

Creating Incentives for Innovators to Modulate their Release of New Large-market Products

Under the prevailing policy paradigm, not only has the technology been limited to large market applications, but arguably the rate of replacing or upgrading those large market applications has slowed. Because of the large payoffs that companies can realize from a single transgenic trait under the strong exclusivity of this policy paradigm, incentives to introduce new products that would compete against one's own existing product are limited. The result of such an incentive structure would be a modulation or reduction of the rate of innovation, particularly for large-market product technologies. The economic problem for innovating companies is effectively one of properly sequencing the introduction of new releases in such a way as to maximize returns,

2. *Although, depending upon the genetic trait, efficacy may improve somewhat at a full-field scale, such as biological insect resistance affecting pest population dynamics.*

given the large fixed costs of achieving regulatory approvals for each new product.

Observations of the innovation cycle in the industry are consistent with this. Effectively, alternatives to the major products of Bt insect resistance or glyphosate herbicide tolerance have not been widely pursued by the initial innovating companies that are profiting from these products in the market. A second-generation version of the glyphosate tolerance trait has been introduced by Monsanto only as the patent life on the initial Roundup Ready trait was nearing its end (Grushkin, 2013) but has been criticized by some as simply a redesign of the original trait in a 'product hopping' tactic (Stumo, 2010).

Virtually Eliminating Public-sector Applications of Biotechnology in Agriculture

Non-profit or public-sector innovators—such as the Consultative Group for International Agricultural Research's international research centers, national agricultural research services, or agricultural research universities—have virtually ceased using biotechnology in their programs developing new crops for humanitarian applications or public release. Over the last couple decades there have been just a handful of high-profile initiatives that, in the end, generated far more discussion than results. These include, of course, the example of *Golden Rice*, a variety engineered to overcome vitamin-A deficiency, which has been in development for well over a decade. This is a version of the technology that would be effective as a nutritional fortification available for close to a decade now (Paine et al., 2005), but it is yet to be released in any market in the world. Other projects, including high nitrogen-use efficiency (NUE) rice for West Africa, have been funded by non-profit organizations such as the Rockefeller Foundation and the Bill and Melinda Gates Foundation and are making, at best, slow progress toward actual cultivation by smallholder farmers for whom the varieties are intended.

We argue again, that it is the distribution of the welfare gains and losses anticipated by various stakeholder groups that have driven the evolution of the policy paradigm into such an alignment as to preclude such humanitarian use applications. Were the policy paradigm of agricultural biotechnology more akin to the policy paradigm of the seed industry, then the precedents of the international crop-breeding programs of the last 50 years might have been effectively augmented by international crop biotechnology programs for alleviating hunger and smallholder poverty. Under the current political economy, such developments continue to be very rare.

Reducing Innovation in Smaller Specialty Crops, Regional Crops, or Product Quality Traits

The corollary of incentives skewing innovation toward large-market, incumbent products is the skewing of innovation away from the much wider range of potential applications of the technology of more moderate profitability. For example, in the US market, transgenic trait development for tomato, potato, and wheat were dropped due to a variety of factors, but in the end it came down to a question of whether payoffs were large enough to justify the large up-front regulatory costs. Innovation has moved away from applications for smaller specialty crops (Bradford et al., 2005; Graff, Wright, Bennett, & Zilberman, 2004), localized or regional agronomic problems, or product quality traits that are necessarily market specific (Graff, Zilberman, & Bennett, 2009).

Consolidating Industry Structure and Thereby Reducing Diversity of Sources of Innovation

The convergence towards the policy paradigm of the pest-control industry has contributed to the consolidation of the industry and a reduction in the diversity of sources of innovation. Today, innovations arising from public-sector R&D or smaller companies only make it onto the marketplace if well aligned with the incumbent firms' R&D interests. In addition, there are four or five companies effectively commercializing transgenic crops in much of the world. The policy paradigm is discouraging entrepreneurship and discouraging venture capital investment in more creative, innovative products. Investors are rational and will not invest in early-stage technology if they do not see a reasonable path to market that can yield a payoff.

Corporations in related markets have also been prompted to abandon R&D in agricultural biotechnology, likely again because of the cost impacts of regulatory competition and control rights issues. In the 1990s a number of large food companies—such as Frito Lay, Campbells, and others—were engaged in crop and food biotechnology R&D. They subsequently rolled back their programs in crop genetics. They are no longer working in these spaces. As a result, the number of companies doing R&D and advancing new crop varieties to the later stages of the R&D pipeline has narrowed to just a few, along with a handful of specialized biotech

entrants, many of which are working in collaboration with one of the big incumbent firms.

Encouraging Development and Utilization of Genetic Methods that Circumvent Current Regulations

In recent years, researchers at an array of companies and public-sector research institutions have begun to utilize next-generation genetic engineering approaches and techniques that appear to "fly under the radar" of current regulatory requirements (Camacho, Van Deynze, Chi-Ham, & Bennett, 2014). These include null segregants, cisgenics/intragenics, and site-directed nucleases. Such techniques have avoided triggering regulatory review in the United States by avoiding or eliminating the genetic elements derived from plant pathogens that are central to first-generation genetic engineering technologies, such as *Agrobacterium*-mediated transformation. Many of the organizations using these techniques are either smaller biotech firms or public-sector institutions rather than the major corporations that currently dominate agricultural biotechnology. Thus, the utilization of these techniques may be a strategy by these smaller organizations to circumvent the costs of the current regulatory system (Camacho et al., 2014).

Proposals for a "Third Way": a Policy Paradigm of Entrepreneurial and Sustainable Agricultural Biotechnology

While highly speculative, it may be feasible to reform the current policy paradigm in a manner that would sufficiently manage the objective risks of genetically engineered crops while enabling the development of many of the traits currently orphaned or disincentivised by policies. The goal of such a policy change would be to enable biotechnology to fulfill its potential in achieving a more sustainable agriculture (Foley et al., 2011; Godfray et al., 2010; Tilman, Cassman, Matson, Naylor, & Polasky, 2002) while maintaining environmental and public health safety, as well as developing vibrant domestic agricultural technology sectors within emerging and developing countries. The major emerging countries—particularly India, China, and Brazil, along with others such as Malaysia, South Africa, Argentina, and Chile—are in opportune positions to benefit from a rationalized policy paradigm that would better serve the economic interest of domestic stakeholders, particularly farmers and consumers. Such a policy would enable these emerging economies to realize their full potential for domestic innovation, building upon their comparative advantages in agriculture.

A 'third way' policy paradigm could combine elements from both the seed industry's policy paradigm and the pesticide industry's policy paradigm.

First would be to increase public funding of crop genetic-development programs. This, together with stronger crop IP, could encourage public researchers and entrepreneurial seed firms to develop and advance useful traits to market. It is one of the most effective ways for governments to increase competition in agricultural inputs and counter market power of established incumbents without distorting markets. Increasing public-sector research and development spending across the full range of relevant disciplines, both in the basic and in the applied agricultural sciences, helps to encourage new lines of investigation. Investment in translational research, drawing results closer to market, helps move the resulting innovations toward the marketplace.

Second, the relative strengthening of the IP could be implemented so as to encourage technology development from public-sector research programs and innovation by smaller entrepreneurs, as opposed to just strengthening the hand of larger corporate interests. The reasoning here is analogous to arguments made regarding the benefits of strengthened property rights in land tenure for the poor and marginalized (De Soto, 2000). In an environment of weak property rights, larger entrenched interests can resort to other means of protecting their market position, whether that includes political connections or the ability to manage the intricacies and costs of the regulatory approvals system. Selectively strengthening the IP regime in plant varietals and crop genetics could, on balance, strengthen the bargaining position of smaller innovators, entrepreneurs, and public-sector research programs engaging in technology transfer and tending to stimulate a wider diversity of innovations moving through the R&D pipeline.

Strengthening of IP is best done by assuring that IP standards are well defined and that scope of individual claims is sharply focused. Patents that make claims that are overly broad in scope or that cover subject matter that is essentially a product of nature can be counterproductive to the goal of stimulating innovation, as individual patents can become a hindrance to making and developing follow-on inventions. It is essential to maintain a system that rewards true invention, with high standards for novelty, non-obviousness, and utility of genetic inventions, which may mean that it is in fact harder to get a patent. However, once granted, such IP protections are more valuable and they can form a

robust basis for market-based transactions in knowledge.

Encouraging public-sector patenting and technology transfer is a way to prime the R&D pipeline and generate a diversity of innovations focused more on creating welfare gains among smallholder farmers or consumers as opposed to the main incentives driving current commercial applications being gains in producer surplus. Also, by orienting the results of public-sector research toward the market, it imposes market discipline in terms of the relevance of public-sector research that is being advanced. It potentially curbs the inefficiencies of public-sector funding officials trying to "pick winners." The key is aligning the programs of public-sector R&D in such a way that options are created for market forces to come in and pick up on innovations to develop further. In particular, the public sector may provide enabling technology platforms, the underlying tool sets that may be needed by smaller companies to engage in smaller-scale market driven innovation (Atkinson et al., 2003; Camacho et al., 2014).

Third, a significantly rationalized regulatory approvals regime could reduce costs by making the primary object of regulation to be the novel phenotype, not the method of genetic development (Bradford et al., 2005). "Rationalized" does not simply mean "thrown out." Rather, regulation of genetically engineered varieties should be calibrated relative to other methods of genetic variation utilized in breeding programs. The regulatory trigger should be driven primarily by the variety's phenotype, thus putting it much more in alignment with the policy paradigm of the seed industry.

An appropriate approach might be to introduce tiered risk categories that differentiate according to potential risks. This would allow greater flexibilities. For example, if a plant variety does contain a novel pest-resistance protein, it may fall into a higher risk category and will be tested for toxicity, allergenicity, and impact on non-target organisms, in accordance with the policy paradigm of the pest-control industry. Other novel traits—for example, a vaccine engineered into the plant—would also fall to the higher risk category and be scrutinized under regulatory requirements for vaccines. However, more minor modifications to the plant genome with a lower risk profile would fall to lower tiers with commensurately lower regulatory requirements and thus lower costs of compliance.

Also, in efforts to rationalize regulatory requirements, it could also be helpful to introduce some sort of exemption or cost-mitigating subsidy to help minor crops, specialty crops, and humanitarian crops. Currently, these face the same high hurdles as major commodity crops. Governments could consider ways to lower the hurdles for smaller market and humanitarian applications, to the extent that they generate welfare gains for consumers or for poor farmers, but little in the way of profits for seed companies.

In conclusion, we have argued that the current alignment of political interests have, in essence, driven agricultural biotechnology into a corner, where high regulatory costs have created high barriers to entry, undermining or capturing contributions of public-sector research, eroding the public mandate to support agricultural innovation, and depriving the benefits of robust market competition and its resulting efficiency improvements and social welfare gains. Our goal is to free up the R&D pipeline so that the potential contributions of innovation in crop genetics for supporting sustainable agriculture can be realized. We have sketched a set of broad brush stroke reform recommendations for creating a "third way" policy paradigm to govern agricultural biotechnology in such a way as to encourage the rate of innovation, particularly in the leading emerging and developing economies.

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